BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of: Pat D. O'Donnell

Serial No.: 10/701,253

Filed: November 4, 2003

Group Art Unit: 3735

Before the Examiner: Hopkins, Christine D.

Title: A SURGICAL INSTRUMENT FOR TREATING FEMALE URINARY STRESS INCONTINENCE

APPEAL BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I. REAL PARTY IN INTEREST

The real party in interest is Pat D. O'Donnell.

II. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellant, Appellant's legal representative or assignee which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1-21 are pending in the Application. Claims 9-17 and 20-21 are withdrawn from consideration. Claims 1-8 and 18-19 stand rejected. Claims 1-8 and 18-19 are appealed.

IV. STATUS OF AMENDMENTS

Appellant has submitted an after-final amendment on September 2, 2008 which was entered by the Examiner on October 24, 2008. The after-final amendment overcame the 35 U.S.C. §112, second paragraph and obviousness-type double-patenting rejections.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent Claim 1:

In one embodiment of the present invention, a surgical instrument for treating female urinary stress incontinence comprising a sling contoured to the anatomical configuration of the mid-urethra, proximal urethra, and base of the bladder for implanting into the lower abdomen of a female. Specification, page 17, lines 9-14; Specification, page 20, lines 1-3; Figure 1, element 3. The sling providing support to mid-urethral and bladder neck sphincteric continence sites as well as support for the base of the bladder. Specification, page 17, lines 15-18. The sling defining in part a tissue remodeling portion fixedly attached to and surrounding a mesh section. Specification, page 17, line 19 – page 18, line 2; Figure 1, elements 10, 11 and 12. The surgical instrument further comprises a sling transfer instrument having a distal end and a proximal end. Specification, page 20, lines 10-14; Figures 5, 5A, elements 52, 53. The instrument defining in part a progressively curved shaft portion positioned between distal and proximal ends with an attached insertion handle located at its proximal end, and a means for attaching the sling to the distal end of the shaft. Specification, page 20, lines 10-14; Specification, page 20, line 19 – page 21, line 2; Figures 5, 5A, elements 51, 52, 53, 54.

Independent Claim 18:

In one embodiment of the present invention, a suprapubic method for treating female urinary stress incontinence comprises providing a sling defining in part a tissue remodeling portion and a mesh section, the sling contoured to the anatomical configuration of the mid-urethra, proximal urethra, and base of the bladder.

Specification, page 17, lines 9-14; Specification, page 20, lines 1-3; Specification, page 23, lines 6-8; Figure 1, elements 3, 10, 11 and 12. The method further comprises providing a first sling transfer instrument having a distal end and a proximal end with a progressively curved shaft portion, the progressively curved shaft portion positioned between the distal and proximal ends and having an insertion handle located at the instrument's proximal end. Specification, page 20, lines 10-14; Specification, page 20, line 19 – page 21, line 2; Specification, page 23, lines 10-12; Figures 5, 5A, elements 51, 52, 53, 54. Additionally, the method comprises positioning the insertion handle of the first sling transfer instrument within the human hand and utilizing the insertion handle to guide a curved tip at the instrument's distal end through the abdominal wall and through the retropubic space, allowing the tip of the instrument to be in contact with the posterior surface of the pubic bone as it traverses the retropubic space and continues into the vagina. Specification, page 22, lines 5-8; Specification, page 23, lines 12-15. Furthermore, the method comprises providing a second sling transfer instrument and repeating step (c) using the second sling transfer instrument. Specification, page 22, lines 15-18; Specification, page 23, lines 16-18. Additionally, the method comprises performing cytoscopy when the curved tip of the first sling transfer instrument and the curved tip of the second sling transfer instrument are positioned within the vagina. Specification, page 23, lines 21-22. Further, the method comprises attaching the sling to the distal end of the first sling transfer instrument and the distal end of the second sling transfer instrument. Specification, page 23, line 22 – page 24, line 3. In addition, the method comprises withdrawing or otherwise positioning the distal end of the first sling transfer instrument and the distal end of the second sling transfer instrument to cause the attached sling to form a U-shape around mid-urethral and bladder neck sphincter continence sites. Specification, page 23, line 22 – page 24, line 3. Further, the method comprises displacing the sling from the first and second sling transfer instruments. Specification, page 24, lines 3-5.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Claims 1, 3, 5-7 and 18-19 stand rejected under 35 U.S.C. §102(e) as being anticipated by Staskin et al. (U.S. Patent Application Publication No. 2003/0045774) (hereinafter "Staskin").

B. Claim 4 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Staskin in view of Bilbo (U.S. Patent Application Publication No. 2002/0103542) (hereinafter "Bilbo").

C. Claims 2 and 8 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Staskin in view of Inman et al. (U.S. Patent Application Publication No. 2003/0065246) (hereinafter "Inman").

VII. ARGUMENT

A. Claims 1, 3, 5-7 and 18-19 are not properly rejected under 35 U.S.C. §102(e).

The Examiner has rejected claims 1, 3, 5-7 and 18-19 under 35 U.S.C. §102(e) as being anticipated by Staskin. Office Action (3/4/2008), page 2. Appellant respectfully traverses for at least the reasons provided below.

For a claim to be anticipated under 35 U.S.C. §102, each and every claim limitation must be found within the cited prior art reference and arranged as required by the claim. M.P.E.P. §2131.

1. Claims 1 and 18 are not anticipated by Staskin.

Appellant respectfully asserts that Staskin does not disclose "a sling contoured to the anatomical configuration of the mid-urethra, proximal urethra, and base of the bladder," as recited in claim 1 and similarly in claim 18. The Examiner cites paragraph [0118] of Staskin as disclosing the above-cited claim limitation. Office Action (3/4/2008), page 3. Appellant respectfully traverses.

Staskin instead discloses a sling that is "preferably rectangular for treating SUI in females . . . ." (Staskin, paragraph [0119], Fig. 4). This type of sling is

commonly referred to as a "tape" sling. As discussed in the disclosure of the present application, such a design "do[es] not restore the normal anatomical relationship of the urinary bladder to the urethra." (Page 9, lines 9–10). By contrast, a contoured sling as claimed "is shaped to restore the normal anatomy of the urethra and base of the bladder," which encourages normal voiding following incontinence surgery. (Page 9, lines 10–13). Further, in the present invention, the normal anatomical position is restored not only of the urethra, but also of the base of the bladder.

There is no language in Staskin that discloses a sling contoured to the anatomical configuration of the mid-urethra, proximal urethra, and base of the bladder. Nor does Staskin disclose the desirability or importance of restoring the normal anatomical relationship of the urinary bladder to the urethra. Therefore, "a sling contoured to the anatomical configuration of the mid-urethra, proximal urethra, and base of the bladder," as recited in claim 1 and similarly in claim 18, is not comparable to simply "a sling capable of being applied to an area beneath and supporting the urethra or bladder neck" as suggested by the Examiner (see page 3 of the Office Action dated 3/4/2008)).

Thus, Staskin does not disclose all of the limitations of claims 1 and 18, and thus Staskin does not anticipate claims 1 and 18. M.P.E.P. §2131.

In response to Appellant's above arguments, the Examiner asserts that the sling of Staskin has dimensions comparable to the instant application. Office Action (3/4/2008), page 9. Appellant respectfully disagrees. Staskin discloses that the sling 42 has a length X, width Y and thickness of approximately within the range of 49 cm to 51 cm, 1.0 cm to 1.2 cm and 0.5808 mm to 0.711 mm, respectively. [0118]. However, Appellant discloses that Appellant's sling 3 is comprised of a generally central segment 5 and distal segments 7 and 8. Page 17, lines 9-10 of Appellant's Specification. The central segment of the tubular mesh sling 3 is approximately 2.5 cm wide and 4.0 cm long with a rapid taper over approximately 1.5 cm down to a size of 1.0 cm in width at distal ends 7 and 8. Page 17, lines 10-12 of Appellant's

Specification. Thus, the sling of Staskin does not include comparable dimensions of the sling of the instant application and there is a structural difference between the claimed invention and the invention of Staskin. Hence, Staskin does not disclose all of the limitations of claims 1 and 18, and thus Staskin does not anticipate claims 1 and 18. M.P.E.P. §2131.

Appellant further asserts that Staskin does not disclose "said instrument defining in part a progressively curved shaft portion positioned between distal and proximal ends with an attached insertion handle located at its proximal end" as recited in claim 1 and similarly in claim 18. The Examiner cites shaft portion 60 of Staskin as disclosing claimed shaft portion. Office Action (3/4/2008), page 3. Appellant respectfully traverses the assertion that Staskin discloses the above-cited claim limitation.

Staskin instead discloses that the radius of the curvature of the needle 60 is substantially constant. [0179]. Hence, the curvature of the needle 60 of Staskin is substantially constant. It is not progressively curved as required by claims 1 and 18. Thus, Staskin does not disclose all of the limitations of claims 1 and 18, and thus Staskin does not anticipate claims 1 and 18. M.P.E.P. §2131.

2. Claim 18 is not anticipated by Staskin.

Appellant respectfully asserts that Staskin does not disclose "positioning the insertion handle of the first sling transfer instrument within the human hand and utilizing the insertion handle to guide a curved tip at the instrument's distal end through the abdominal wall and through the retropubic space, allowing the tip of the instrument to be in contact with the posterior surface of the pubic bone as it traverses the retropubic space and continues into the vagina" as recited in claim 18. The Examiner cites paragraphs [0219-0222] of Staskin as disclosing the above-cited claim limitations. Office Action (3/4/2008), page 4. Further, the Examiner cited to element 46 of Staskin as disclosing the claimed first sling transfer instrument and cited to

element 64 as disclosing the claimed insertion handle. *Id.* at page 3. Appellant respectfully traverses.

Staskin instead discloses that the surgeon typically holds the handle 64 of the needle 60 during this time by using predominantly one hand. [0222]. Furthermore, Staskin discloses that optionally, with the index finger of the opposite hand, the surgeon may meet the end 58 of the needle via the paraurethral dissection. [0222]. Additionally, Staskin discloses that the surgeon's finger may be delicately placed adjacent endopelvic fascia of the patient and used to guide the needle 60 through the relatively tough endopelvic fascia and into the vaginal incision 404. [0222].

Hence, Staskin discloses that the surgeon holds the handle 64 of the needle 60 while at the same time uses the index finger of the opposite hand to guide the needle 60 through the relatively tough endopelvic fascia and into the vaginal incision.

There is no language in the cited passages that discloses positioning the insertion handle of the first sling transfer instrument within the human hand and utilizing the insertion handle to guide a curved tip at the instrument's distal end through the abdominal wall and through the retropubic space. Instead, Staskin discloses the surgeon using the index finger of the opposite hand to guide the needle 60 through the relatively tough endopelvic fascia and into the vaginal incision. Neither is there any language in the cited passages that discloses positioning the insertion handle of the first sling transfer instrument within the human hand and utilizing the insertion handle to guide a curved tip at the instrument's distal end through the abdominal wall and through the retropubic space allowing the tip of the instrument to be in contact with the posterior surface of the pubic bone as it traverses the retropubic space and continues into the vagina.

Thus, Staskin does not disclose all of the limitations of claim 18, and thus Staskin does not anticipate claim 18. M.P.E.P. §2131.

Appellant further asserts that Staskin does not disclose "providing a second sling transfer instrument and repeating step (c) using the second sling transfer

instrument" as recited in claim 18. The Examiner asserts that the steps are repeated with a second needle 60. Office Action (3/4/2008), page 4. Appellant respectfully traverses.

Staskin discloses that the steps described above are repeated as needed for a second needle 60 on the other side of the urethra 16. [0224]. However, this is not the same as a second sling transfer instrument. The Examiner had previously cited sling assembly 46 as disclosing the claimed sling transfer instrument. Office Action (3/4/2008), page 3. Hence, the Examiner must cite to language in Staskin that discloses a second sling assembly 46. Further, claim 18 recites repeating step (c) using the second sling transfer instrument. There is no language in Staskin that discloses positioning the insertion handle of a second sling transfer instrument within the human hand and utilizing the insertion handle to guide a curved tip at the instrument's distal end through the abdominal wall and through the retropubic space, allowing the tip of the instrument to be in contact with the posterior surface of the pubic bone as it traverses the retropubic space and continues into the vagina. Instead, Staskin discloses that the surgeon uses the index finger of the opposite hand to guide the second needle 60 through the relatively tough endopelvic fascia and into the vaginal incision.

Thus, Staskin does not disclose all of the limitations of claim 18, and thus Staskin does not anticipate claim 18. M.P.E.P. §2131.

Appellant further asserts that Staskin does not disclose "attaching the sling to the distal end of the first sling transfer instrument and the distal end of the second sling transfer instrument" as recited in claim 18. The Examiner cites paragraph [0028] of Staskin as disclosing the above-cited claim limitation. Office Action (3/4/2008), page 4. Appellant respectfully traverses.

[0028] of Staskin is unrelated to attaching a sling to a distal end of a sling transfer instrument. Staskin discloses that the two ends 48, 50 of the elongate sling assembly 46 attach to a first end 52 of a dilator 54 or needle-sling connector. [0115].

There is no language in Staskin that discloses attaching the sling to the distal end of the first sling transfer instrument and the distal end of the second sling transfer instrument. There is no language in Staskin that discusses attaching the sling to the distal ends of the first and second sling transfer instruments.

Thus, Staskin does not disclose all of the limitations of claim 18, and thus Staskin does not anticipate claim 18. M.P.E.P. §2131.

Appellant further asserts that Staskin does not disclose "withdrawing or otherwise positioning the distal end of the first sling transfer instrument and the distal end of the second sling transfer instrument to cause the attached sling to form a U-shape around mid-urethral and bladder neck sphincter continence sites" as recited in claim 18. The Examiner has not addressed this claim limitation. Appellant reviewed the entire reference of Staskin and could not locate any language that suggested the above-cited claim limitation. The Examiner is reminded that in order to establish a *prima facie* case of anticipation, the Examiner must provide a single prior art reference that expressly or inherently describes each and every element as set forth in the claim. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Since the Examiner has not addressed this limitation, the Examiner has not established a *prima facie* case of anticipation in rejecting claim 18. M.P.E.P. §2131.

Appellant further asserts that Staskin does not disclose "displacing the sling from the first and second sling transfer instruments" as recited in claim 18. The Examiner has not addressed this claim limitation. Appellant reviewed the entire reference of Staskin and could not locate any language that suggested the above-cited claim limitation. The Examiner is reminded that in order to establish a *prima facie* case of anticipation, the Examiner must provide a single prior art reference that expressly or inherently describes each and every element as set forth in the claim. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Since the Examiner has not addressed this limitation,

the Examiner has not established a *prima facie* case of anticipation in rejecting claim 18. M.P.E.P. §2131.

3. Claims 3 and 5-7 are not anticipated by Staskin for at least the reasons that claim 1 is not anticipated by Staskin.

Claims 3 and 5-7 each recite combinations of features of independent claim 1, and hence claims 3 and 5-7 are not anticipated by Staskin for at least the above-stated reasons that claim 1 is not anticipated by Staskin.

4. Claim 5 is not anticipated by Staskin.

Appellant further asserts that Staskin does not disclose "wherein the mesh section is approximately 60 cm in length, approximately 1.5 cm to 3.0 cm at its widest and generally center-most position, and approximately 1.0 cm wide at each of its opposite ends" as recited in claim 5. The Examiner cites paragraph [0118] of Staskin as disclosing the above-cited claim limitation. Office Action (3/4/2008), page 3. Appellant respectfully traverses.

Staskin instead discloses that the associated sling 42 has a length X, width Y and thickness approximately within the range of 49 cm to 51 cm, 1.0 cm to 1.2 cm and 0.508 mm to 0.711 mm, respectively. [0118].

Hence, Staskin discloses that sling 42 has a length within the range of 49 cm to 51 cm, a width within the range of 1.0 cm to 1.2 cm and a thickness within the range of 0.508 mm and 0.711 mm.

There is no language in the cited passage that discloses that the mesh section of the sling has a length of approximately 60 cm. Neither is there any language in the cited passage that discloses that the mesh section of the sling is approximately 1.5 cm to 3.0 cm at its widest and generally center-most position. Neither is there any language in the cited passage that discloses that the mesh section of the sling is approximately 1.0 cm wide at each of its opposite ends.

Thus, Staskin does not disclose all of the limitations of claim 5, and thus

Staskin does not anticipate claim 5. M.P.E.P. §2131.

5. Claim 6 is not anticipated by Staskin.

Appellant respectfully asserts that Staskin does not disclose "wherein the progressively curved shaft portion has a diameter of approximately 3.5 millimeters (mm) to 4.0 mm and a progressive curve with a maximum radius of approximately 5.1 cm" as recited in claim 6. The Examiner cites needle 60 of Staskin as disclosing the claimed shaft portion. Office Action (3/4/2008), page 3. Appellant traverses the assertion that Staskin discloses the above-cited claim limitation.

Staskin instead discloses that the length N of the needle 60 is approximately within the range of 16.5 cm to 24.1 cm (6.5 inches to 9.5 inches) and has a preferred external diameter of approximately 3.175 mm (0.125 inch). [0177]. Staskin further discloses that the radius of the curvature of the needle 60 is substantially constant. [0179].

There is no language in Staskin that discloses that needle 60 of Staskin (Examiner asserts that needle 60 of Staskin discloses the claimed curved shaft portion) has a diameter of approximately 3.5 mm to 4.0 mm. Instead, Staskin discloses that needle 60 of Staskin has an external diameter of approximately 3.175 mm. Further, there is no language in Staskin that discloses that needle 60 of Staskin (Examiner asserts that needle 60 of Staskin discloses the claimed curved shaft portion) has a progressive curve with a maximum radius of approximately 5.1 cm. As discussed above, Staskin instead discloses that needle 60 of Staskin has an external diameter of approximately 3.175 mm. Further, the curvature of the needle 60 is substantially constant. It is not progressively curved. And it does not have a progressive curve with a maximum radius of approximately 5.1 cm.

Thus, Staskin does not disclose all of the limitations of claim 6, and thus Staskin does not anticipate claim 6. M.P.E.P. §2131.

6. Claim 7 is not anticipated by Staskin.

Appellant respectfully asserts that Staskin does not disclose "wherein the distal end of the sling transfer instrument is oriented in a direction opposite that of the progressively curved shaft portion, the distal end of the progressively curved shaft portion being approximately 1.0 cm in length and approximately 4.0 mm in width" as recited in claim 7. The Examiner cites needle 60 of Staskin as disclosing the claimed curved shaft portion. Office Action (3/4/2008), pages 3-4. The Examiner further cites Figure 4 of Staskin as disclosing the above-cited claim limitation. *Id.* at page 4. Appellant respectfully traverses.

Staskin instead discloses that Figure 4 illustrates a sling assembly 46 that includes a sling 42 for treating incontinence. [0113]. Staskin further discloses that each of the two ends 48, 50 of the elongate sling assembly 46 attaches to a first end 52 of a dilator 54 or needle-sling connector. [0115]. Further, Staskin discloses that the dilator 54 dilates a needle track for ease of sling introduction and positioning within the patient. [0115].

There is no language in the description of Figure 4 or depicted in Figure 4 of Staskin that discloses that the distal end of the sling transfer instrument (Examiner asserts that sling assembly 46 of Staskin discloses the claimed sling transfer instrument) is oriented in a direction opposite that of the progressively curved shaft portion. How is sling transfer instrument 46 oriented in a direction opposite that of needle 60 (Examiner asserts that needle 60 discloses the claimed progressively curved shaft portion)? Figure 4 does not illustrate that sling transfer instrument 46 is oriented in a direction opposite that of needle 60. Further, there is no language in the description of Figure 4 or depicted in Figure 4 of Staskin that discloses that the distal end of the sling transfer instrument (Examiner asserts that sling assembly 46 of Staskin discloses the claimed sling transfer instrument) is oriented in a direction opposite that of the progressively curved shaft portion, the distal end of the progressively curved shaft portion being approximately 1.0 cm in length and approximately 4.0 mm in width. The Examiner has not pointed to any language in Staskin as disclosing the distal end of needle 60 (Examiner asserts that needle 60

discloses the claimed progressively curved shaft portion) being approximately 1.0 cm in length and approximately 4.0 mm in width.

Thus, Staskin does not disclose all of the limitations of claim 7, and thus Staskin does not anticipate claim 7. M.P.E.P. §2131.

B. Claim 4 is not properly rejected under 35 U.S.C. §103(a) as being unpatentable over Staskin in view of Bilbo.

The Examiner has rejected claim 4 under 35 U.S.C. §103(a) as being unpatentable over Staskin view of Bilbo. Office Action (3/4/2008), page 5. Appellant respectfully traverses for at least the reasons stated below.

1. Claim 4 is patentable over Staskin in view of Bilbo for at least the reasons that claim 1 is not anticipated by Staskin.

Claim 4 recites the combinations of features of independent claim 1, and hence claim 4 is patentable over Staskin in view of Bilbo for at least the above-stated reasons that claim 1 is not anticipated by Staskin.

2. Claim 4 is patentable over Staskin in view of Bilbo.

Appellant respectfully asserts that Staskin and Bilbo, taken singly or in combination, do not teach "wherein the mesh section is comprised of absorbable polymers and filaments of the mesh section have a diameter of approximately .012 inch to 0.1 inch" as recited in claim 4. The Examiner cites paragraph [0040] of Bilbo as teaching the above-cited claim limitation. Office Action (3/4/2008), page 5. Appellant respectfully traverses.

Bilbo instead teaches that the surgical sling consists of a five-layer laminated sheet of porcine intestinal collagen, about 0.20 mm to about 0.25 mm in thickness. [0040].

Hence, Bilbo teaches a surgical sling that consists of a **five-layer laminated sheet of porcine intestinal collagen**. Porcine refers to a swine. See http://www.merriam-webster.com/dictionary/porcine. Collagen is the main protein of

connective tissue in animals and the most abundant protein in mammals making up about 25% to 35% of the whole-body protein content. See http://en.wikipedia.org/wiki/Collagen. The cited passage does not teach a mesh section comprised of absorbable polymers. Furthermore, Bilbo discloses a thickness between .2 mm and .25 mm. This corresponds to .00787 inches and .0098 inches, respectively. See http://www.convertunits.com/from/mm/to/inches. Hence, Bilbo does not disclose a mesh section comprised of absorbable polymers and filaments of the mesh section having a diameter of approximately .012 inch to 0.1 inch.

Therefore, the Examiner has not presented a *prima facie* case of obviousness in rejecting claim 4, since the Examiner is relying upon incorrect, factual predicates in support of the rejection. *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1455 (Fed. Cir. 1998).

3. Examiner's reasoning for modifying Staskin with Bilbo to include the missing claim limitation of claim 4 is insufficient to establish a *prima facie* case of obviousness.

Most if not all inventions arise from a combination of old elements. *See In re Rouffet*, 47 U.S.P.Q.2d 1453, 1457 (Fed. Cir. 1998). Obviousness is determined from the vantage point of a hypothetical person having ordinary skill in the art to which the patent pertains. *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1457 (Fed. Cir. 1998). Therefore, an Examiner may often find every element of a claimed invention in the prior art. *Id.* However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. *See Id.* In order to establish a *prima facie* case of obviousness, the Examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed. *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1458 (Fed. Cir. 1998). The Examiner must provide articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (cited approvingly in *KSR International Co. v. Teleflex Inc.*, 82 U.S.P.Q.2d 1385, 1396 (U.S. 2007)).

As understood by Appellant, the Examiner admits that Staskin does not teach "wherein the mesh section is comprised of absorbable polymers and filaments of the mesh section have a diameter of approximately .012 inch to 0.1 inch" as recited in claim 4. Office Action (3/4/2008), page 5. The Examiner asserts that Bilbo teaches the above-cited claim limitation. *Id.* The Examiner's reasoning for modifying Staskin with Bilbo to include the above-cited claim limitation is because the mesh sling will naturally degrade within the patient yet provide support to the urethra for treating urinary incontinence. *Id.* The Examiner's reasoning is insufficient to establish a *prima facie* case of obviousness in rejecting claim 4.

The Examiner has not provided any rational underpinning as to how the Examiner derived his motivation for modifying Staskin to include the above-cited missing claim limitation. The Examiner simply states "because the mesh sling will naturally degrade within the patient yet provide support to the urethra for treating urinary incontinence" as reasoning for modifying Staskin to include the above-cited claim limitation. While the Examiner may consider many factors in finding a reason to combine, the Examiner still must explain how the Examiner derived the reasoning for modifying Staskin to include the above-cited missing claim limitation. *KSR International Co. v. Teleflex Inc.*, 82 U.S.P.Q.2d 1385, 1396 (U.S. 2007). The Examiner appears to be relying upon his own subjective opinion which is insufficient to support a *prima facie* case of obviousness. *In re Lee*, 61 U.S.P.Q.2d 1430, 1434 (Fed. Cir. 2002). Consequently, the Examiner's reasoning for modifying Staskin to include the missing claim limitation of claim 4 is insufficient to support a *prima facie* case of obviousness for rejecting claim 4. *Id.*

Further, the Examiner's reasoning ("because the mesh sling will naturally degrade within the patient yet provide support to the urethra for treating urinary incontinence") does not provide reasons, as discussed further below, that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would modify Staskin to include the above-indicated missing claim limitation of claim 4. Accordingly, the Examiner has not presented a *prima*

facie case of obviousness for rejecting claim 4. *KSR International Co. v. Teleflex Inc.*, 82 U.S.P.Q.2d 1385, 1396 (U.S. 2007); *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1458 (Fed. Cir. 1998).

Staskin addresses the problem of developing a surgical instrument suitable for incontinence procedures. [0002-0015]. The Examiner has not provided any reasons as to why one skilled in the art would modify Staskin (which addresses the problem of developing a surgical instrument suitable for incontinence procedures) to have a mesh section comprised of absorbable polymers and filaments of the mesh section having a diameter of approximately .012 inch to 0.1 inch (missing claim limitation). The Examiner's rationale ("because the mesh sling will naturally degrade within the patient yet provide support to the urethra for treating urinary incontinence") does not provide such reasoning.

What is the rational connection between having a mesh section comprised of absorbable polymers and filaments of the mesh section having a diameter of approximately .012 inch to 0.1 inch (missing claim limitation) and because the mesh sling will naturally degrade within the patient yet provide support to the urethra for treating urinary incontinence (Examiner's reasoning)? How does the fact that the mesh sling will naturally degrade relate to the fact that the mesh section be comprised of absorbable polymers and filaments of the mesh section having a diameter of approximately .012 inch to 0.1 inch?

Hence, the Examiner's rationale does not provide reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would modify Staskin to include the above-cited missing claim limitation of claim 4. Accordingly, the Examiner has not presented a *prima facie* case of obviousness for rejecting claim 4. *KSR International Co. v. Teleflex Inc.*, 82 U.S.P.Q.2d 1385, 1396 (U.S. 2007); *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1458 (Fed. Cir. 1998).

C. Claims 2 and 8 are not properly rejected under 35 U.S.C. §103(a) as

being unpatentable over Staskin view of Inman.

1. Claims 2 and 8 are patentable over Staskin in view of Inman for at least the reasons that claim 1 is not anticipated by Staskin.

Claims 2 and 8 recite the combinations of features of independent claim 1, and hence claims 2 and 8 are patentable over Staskin in view of Inman for at least the above-stated reasons that claim 1 is not anticipated by Staskin.

2. Claim 2 is patentable over Staskin in view of Inman.

Appellant respectfully asserts that Staskin and Inman, taken singly or in combination, do not teach "wherein the insertion handle further comprises a digit control accommodation, said digit control accommodation dimensioned approximately 2.5 to 4.5 centimeters (cm) in length, 1.0 to 4.0 cm in width and 1.5 cm in depth" as recited in claim 2. The Examiner cites paragraphs [0046, 0051 and 0053] of Inman as teaching the above-cited claim limitations. Office Action (3/4/2008), page 6. Appellant respectfully traverses.

Inman instead teaches that the handle 12 has a major anterior surface 64 that is best seen in Figure 4. [0046]. Inman further teaches that the height H of the handle 12 is preferably between about 3.25 inches and about 4.75 inches. [0046]. Furthermore, Inman teaches that the handle 12 has a longitudinal axis A along its height H, where the handle 12 preferably includes an elongate channel 32 extending across the width W of the handle 12. [0051]. Additionally, Inman teaches that the channel 32 has an axis that extends substantially perpendicular to the longitudinal axis A of the handle 12. [0051]. Further, Inman teaches that the height (length) of the channel 32 along the longitudinal axis A of the handle 12 is more than 0.5 inches and less than 1 inch, more preferably the length is about 0.9 inches and that the depth of the channel 32 is preferably between 25% and 100% of the depth of the handle 12. [0051]. In addition, Inman teaches that the height H to width W ratio of the handle 12 is preferably greater than 3:1, and the depth D to width W ratio is preferably less than 1:2. [0053].

Hence, Inman teaches that handle 12 preferably includes an elongate channel 32 extending across the width W of the handle 12, where the height (length) of the channel 32 along the longitudinal axis A of the handle 12 is more than 0.5 inches and less than 1 inch, more preferably the length is about 0.9 inches and that the depth of the channel 32 is preferably between 25% and 100% of the depth of the handle 12. Inman further teaches that the height H to width W ratio of the handle 12 is preferably greater than 3:1, and the depth D to width W ratio is preferably less than 1:2.

There is no language in the cited passages that teaches an insertion handle that comprises a digit control accommodation. If the Examiner is asserting that channel 32 of Inman corresponds to the claimed digital control accommodation, Appellant respectfully requests the Examiner to provide a basis in fact and/or technical reasoning to support such an assertion. *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). That is, the Examiner must provide extrinsic evidence that must make clear that channel 32 of Inman corresponds to the claimed digital control accommodation, and that it would be so recognized by persons of ordinary skill. *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999). Since the Examiner has not provided any such objective evidence, the Examiner has not presented a *prima facie* case of obviousness for rejecting claim 2. M.P.E.P. §2112.

Further, there is no language in the cited passages that teaches a digit control accommodation dimensioned approximately 2.5 to 4.5 centimeters (cm) in length, 1.0 to 4.0 cm in width and 1.5 cm in depth. Instead, Inman teaches that the length of channel 32 is between 0.5 inches (1.3 cm) and 1.0 inches (2.5 cm). See http://manuelsweb.com/in_cm.htm. Further, Inman teaches that the H to width W ratio of the handle 12 is preferably greater than 3:1, hence, one may assume that the width of channel 32 to be between .43 cm and .83 cm.

Therefore, the Examiner has not presented a *prima facie* case of obviousness in rejecting claim 2, since the Examiner is relying upon incorrect, factual predicates in support of the rejection. *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1455 (Fed. Cir. 1998).

3. Examiner's reasoning for modifying Staskin with Inman to include the missing claim limitation of claim 2 is insufficient to establish a *prima facie* case of obviousness.

As stated above, most if not all inventions arise from a combination of old elements. *See In re Rouffet*, 47 U.S.P.Q.2d 1453, 1457 (Fed. Cir. 1998). Obviousness is determined from the vantage point of a hypothetical person having ordinary skill in the art to which the patent pertains. *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1457 (Fed. Cir. 1998). Therefore, an Examiner may often find every element of a claimed invention in the prior art. *Id.* However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. *See Id.* In order to establish a *prima facie* case of obviousness, the Examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed. *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1458 (Fed. Cir. 1998). The Examiner must provide articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (cited approvingly in *KSR International Co. v. Teleflex Inc.*, 82 U.S.P.Q.2d 1385, 1396 (U.S. 2007)).

As understood by Appellant, the Examiner admits that Staskin does not teach "wherein the insertion handle further comprises a digit control accommodation, said digit control accommodation dimensioned approximately 2.5 to 4.5 centimeters (cm) in length, 1.0 to 4.0 cm in width and 1.5 cm in depth" as recited in claim 2. Office Action (3/4/2008), page 6. The Examiner asserts that Inman teaches the above-cited claim limitation. *Id.* The Examiner's reasoning for modifying Staskin with Inman to include the above-cited claim limitation is "in an effort to provide a stable construction for a surgeon's finger when inserting a sling within a patient during a surgical procedure." *Id.* The Examiner's reasoning is insufficient to establish a *prima facie* case of obviousness in rejecting claim 2.

The Examiner has not provided any rational underpinning as to how the Examiner derived his motivation for modifying Staskin to include the above-cited missing claim limitation. The Examiner simply states "in an effort to provide a stable construction for a surgeon's finger when inserting a sling within a patient during a surgical procedure" as reasoning for modifying Staskin to include the above-cited claim limitation. While the Examiner may consider many factors in finding a reason to combine, the Examiner still must explain how the Examiner derived the reasoning for modifying Staskin to include the above-cited missing claim limitation. *KSR International Co. v. Teleflex Inc.*, 82 U.S.P.Q.2d 1385, 1396 (U.S. 2007). The Examiner appears to be relying upon his own subjective opinion which is insufficient to support a *prima facie* case of obviousness. *In re Lee*, 61 U.S.P.Q.2d 1430, 1434 (Fed. Cir. 2002). Consequently, the Examiner's reasoning for modifying Staskin to include the missing claim limitation of claim 2 is insufficient to support a *prima facie* case of obviousness for rejecting claim 2. *Id.*

Further, the Examiner's reasoning ("in an effort to provide a stable construction for a surgeon's finger when inserting a sling within a patient during a surgical procedure") does not provide reasons, as discussed further below, that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would modify Staskin to include the above-indicated missing claim limitation of claim 2. Accordingly, the Examiner has not presented a *prima facie* case of obviousness for rejecting claim 2. *KSR International Co. v. Teleflex Inc.*, 82 U.S.P.Q.2d 1385, 1396 (U.S. 2007); *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1458 (Fed. Cir. 1998).

Staskin addresses the problem of developing a surgical instrument suitable for incontinence procedures. [0002-0015]. The Examiner has not provided any reasons as to why one skilled in the art would modify Staskin (which addresses the problem of developing a surgical instrument suitable for incontinence procedures) to have an insertion handle comprise a digit control accommodation, the digit control accommodation dimensioned approximately 2.5 to 4.5 centimeters (cm) in length, 1.0

to 4.0 cm in width and 1.5 cm in depth (missing claim limitation). The Examiner's rationale ("in an effort to provide a stable construction for a surgeon's finger when inserting a sling within a patient during a surgical procedure") does not provide such reasoning. The Examiner has not provided any evidence that by having a digital control accommodation dimensioned as set forth in claim 2 that it will provide a stable construction for a surgeon's finger when inserting a sling within a patient during a surgical procedure using the sling of the present invention of Staskin.

Hence, the Examiner's rationale does not provide reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would modify Staskin to include the above-cited missing claim limitation of claim 2. Accordingly, the Examiner has not presented a *prima facie* case of obviousness for rejecting claim 2. *KSR International Co. v. Teleflex Inc.*, 82 U.S.P.Q.2d 1385, 1396 (U.S. 2007); *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1458 (Fed. Cir. 1998).

VIII. CONCLUSION

For the reasons noted above, the rejections of claims 1-8 and 18-19 are in error. Appellant respectfully requests reversal of the rejections and allowance of claims 1-8 and 18-19.

Respectfully submitted,

WINSTEAD P.C.

Attorneys for Appellant

By: _____

Robert A. Voigt, Jr.
Reg. No. 47,159

P.O. Box 50784
Dallas, Texas 75201
(512) 370-2832

CLAIMS APPENDIX

1. A surgical instrument for treating female urinary stress incontinence comprising:

a) a sling contoured to the anatomical configuration of the mid-urethra, proximal urethra, and base of the bladder for implanting into the lower abdomen of a female; the sling providing support to mid-urethral and bladder neck sphincteric continence sites as well as support for the base of the bladder, said sling defining in part a tissue remodeling portion fixedly attached to and surrounding a mesh section; and

b) a sling transfer instrument having a distal end and a proximal end, said instrument defining in part a progressively curved shaft portion positioned between distal and proximal ends with an attached insertion handle located at its proximal end, and a means for attaching said sling to the distal end of said shaft.

2. The surgical instrument of claim 1 wherein the insertion handle further comprises a digit control accommodation, said digit control accommodation dimensioned approximately 2.5 to 4.5 centimeters (cm) in length, 1.0 to 4.0 cm in width and 1.5 cm in depth.

3. The surgical instrument of claim 1 wherein the mesh section is comprised of non-absorbable polymers and filaments of the mesh section have a diameter of approximately .002 inch to .08 inch.

4. The surgical instrument of claim 1 wherein the mesh section is comprised of absorbable polymers and filaments of the mesh section have a diameter of approximately .012 inch to 0.1 inch.

5. The surgical instrument of claim 1 wherein the mesh section is approximately 60 cm in length, approximately 1.5 cm to 3.0 cm at its widest and generally center-most position, and approximately 1.0 cm wide at each of its opposite ends.

6. The surgical instrument of claim 1 wherein the progressively curved shaft portion has a diameter of approximately 3.5 millimeters (mm) to 4.0 mm and a progressive curve with a maximum radius of approximately 5.1 cm.

7. The surgical instrument of claim 1 wherein the distal end of the sling transfer instrument is oriented in a direction opposite that of the progressively curved shaft portion, the distal end of the progressively curved shaft portion being approximately 1.0 cm in length and approximately 4.0 mm in width.

8. The surgical instrument of claim 1 wherein the progressively curved shaft is further comprised of a luminous coating.

18. A suprapubic method for treating female urinary stress incontinence comprising:

a) providing a sling defining in part a tissue remodeling portion and a mesh section, the sling contoured to the anatomical configuration of the mid-urethra, proximal urethra, and base of the bladder;

b) providing a first sling transfer instrument having a distal end and a proximal end with a progressively curved shaft portion, the progressively curved shaft portion positioned between the distal and proximal ends and having an insertion handle located at the instrument's proximal end;

c) positioning the insertion handle of the first sling transfer instrument within the human hand and utilizing the insertion handle to guide a curved tip at the instrument's distal end through the abdominal wall and through the retropubic space, allowing the tip of the instrument to be in contact with the posterior surface of the pubic bone as it traverses the retropubic space and continues into the vagina;

d) providing a second sling transfer instrument and repeating step (c) using the second sling transfer instrument;

e) performing cytoscopy when the curved tip of the first sling transfer instrument and the curved tip of the second sling transfer instrument are positioned within the vagina;

f) attaching the sling to the distal end of the first sling transfer instrument and the distal end of the second sling transfer instrument;

g) withdrawing or otherwise positioning the distal end of the first sling transfer instrument and the distal end of the second sling transfer instrument to cause the attached sling to form a U-shape around mid-urethral and bladder neck sphincter continence sites; and

h) displacing the sling from the first and second sling transfer instruments.

19. The method of claim 18 further comprising the adjusting of sling tension via a sling tension measurement component.

EVIDENCE APPENDIX

No evidence was submitted pursuant to §§1.130, 1.131, or 1.132 of 37 C.F.R. or of any other evidence entered by the Examiner and relied upon by Appellant in the Appeal.

RELATED PROCEEDINGS APPENDIX

There are no related proceedings to the current proceeding.